

JUL 22 2003

**9.0 510(k) Summary**

Applicant Name: EKOS Corporation

Address: 22030 20<sup>th</sup> Ave. SE, Suite 101  
Bothell, WA 98021

Contact Person: Jocelyn Kersten  
Regulatory Affairs Manager

Telephone: (425) 482-1108 X 287

Fax: (425) 482-1109

Device: EKOS Peripheral Infusion System

Classification: CFR 870.1210 – Continuous Flush Catheter

Panel: Cardiovascular

Product Code: KRA

Intended Use: The Peripheral Infusion System is intended for the controlled and selective infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature.

Device Description: The EKOS Peripheral Infusion System is an infusion catheter system designed to deliver ultrasound energy through a transducer element at the distal catheter tip. This device is intended to deliver physician-specified agents or fluids into the peripheral vasculature.

Predicate Basis: The EKOS Peripheral Infusion System is substantially equivalent to other legally marketed devices. These devices include

- Boston Scientific Corporation: Renegade Hi-Flo Microcatheter (K000177)
- Boston Scientific Corporation: TurboTracker 18 Infusion Catheter (K960806)
- Boston Scientific Corporation: FasTracker Infusion Catheter (K926243)
- Bacchus Vascular, Inc.: Trellis Infusion System (K023514)
- AngioDynamics: Pulse Spray Infusion System PRO Infusion Catheter (K950907)
- JoMed: PV 0.018 F/X (K944004)

Performance: EKOS has conducted preclinical bench and animal studies with the

Peripheral Infusion System. These studies demonstrate that the performance of the Peripheral Infusion System meets its design specifications and is safe and effective for its intended use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

**JUL 22 2003**

EKOS Corp.  
c/o Ms. Jocelyn Kersten  
22030 20<sup>th</sup> Ave SE, Suite 101  
Bothell, WA 98021

Re: K030637  
EKOS Peripheral Infusion System  
Regulation Number: 21 CFR 870.1210  
Regulation Name: Catheter, Continuous Flush  
Regulatory Class: Class II (two)  
Product Code: KRA  
Dated: June 20, 2003  
Received: June 23, 2003

Dear Ms. Kersten:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

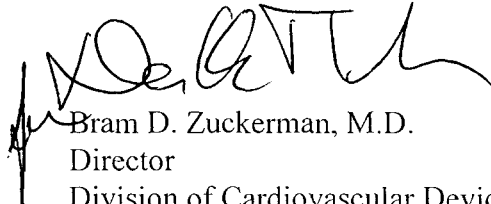
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "B. Zuckerman", is written over the printed name.

Bram D. Zuckerman, M.D.  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

1.10 Indications for Use Statement

EKOS Corporation  
22030 20<sup>th</sup> Ave. SE, Suite 101  
Bothell, WA 98021

Indications for Use Statement

510(k) Number (if known): K030637

Device Name: EKOS Peripheral Infusion System

*Indications for Use:*

The EKOS Peripheral Infusion System is intended for the controlled and selective infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature.

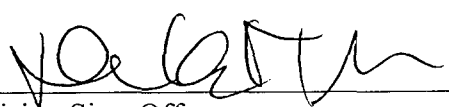
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

  
\_\_\_\_\_  
Division Sign-Off  
Division of Cardiovascular Devices

510(k) Number K030637